5. 510(k) Summary

[As Required by 21 CFR 807.87(h) & 21 CFR 807.92]

1. Submission information

Name of Company: OTIS Biotech Co., Ltd
FDA registration No. 3005140381
#514 Sihwa industrial complex 2Ba Block
Jeongwang-Dong, Siheung-si
Gyounggi-Do, Republic of Korea 429-450
Tel: 82-31-319-0406
Fax: 82-31-319-0414

Contact: srinivasareddy krotha
E-mail: srinivasareddy@otisbiotech.com
Tel: 82-31-414-4618
Fax: 82-31-411-1076

Date Prepared: 10-05-2010

2. Device Identification

Trade Name: MultiFit™ Total Hip System
Common Name: Total Hip Joint Prosthesis
Classification: **Class Ⅱ (Special Control)**
JDI 888.3350 – Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented.
LZO 888.3353 –Hip joint metal/ceramic/polymer semi -constrained cemented or nonporous un cemented prosthesis
KWY 888.3390 - Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented or Uncemented
KWZ 888.3310 - Prosthesis, Hip, Constrained, Cemented or uncemented, Metal/Polymer

3. Substantial Equivalence Predicate Legally Marketed Devices

The substantial equivalence of this device is based on equivalence in

intended use, materials, designs and operational principles to the below listed predicate devices.

OTIS Biotech Co., Ltd MultiFit™ Total Hip System	**Predicate Device**	**510(k) Approval Number**	**Product Code**
Cementless Tapered Stem	i) Depuy Orthopaedicss, Inc. Summit™ DuoFix™ Hip Prosthesis	K011489	LPH
	ii) Osteonics corporation. Osteonics Imnifit HA Hip stem series	K982032	MEH
Cement Collared Stem	i) Wright Medical Technology INC. PERFECTA® IMC Hip System	K972641	JDI
	ii) Smith & Nephew, Inc. Synergy Cemented Hip stem	K990369	LPH
Acetabular System	i) Zimmer, Inc. Trilogy Acetabular System	K934765	LPH
	ii) Smith & Nephew, Inc. Reflection Cross-linked UHMWPE acetabular component	K002747	LPH, JDI
Bipolar System	i) Depuy, Inc. Self-centering Hip prosthesis	K812672	KWY
	ii) Biomet, Inc. Ringloc Bi-polar acetabular component	K051569	JID
Femoral Ball Head	i) Smith & Nephew, Inc. Total Hip Femoral Head – 12/14 Taper	K021673	LZO
	ii) Biomet, Inc. Biomet Cobalt-chrome femoral components	K911684	JDI
Bone Screw	Zimmer, Inc. Trilogy Acetabular System	K934765	LPH

4. Device Description

The MultiFit™ Total Hip System is total hip joint prosthesis which consists of stems, acetabular system, bipolar system and femoral head. Stems are available with two femoral designs. One is manufactured from Ti6Al4V alloy which intended for non-cemented use. The other femoral component design is manufactured from CoCrMo and is intended for cemented use. All implant devices are designed for single use only and provided with separated sterilized package. Various sizes are available for each component.

Femoral stems – Cementless stem (sizes 130 mm to 150 mm) and cement collared stem (sizes 110 mm to 128 mm) are intended to be used with the other components of the The MultiFit™ Total Hip

Metal femoral heads – Metal femoral heads (22 mm and 28 mm in diameter) which is fabricated from Cobalt Chromium Molybdenum (CoCrMo) are intended to be used in conjunction with the commercially available press-fit Ti6Al4V or Co-Cr-Mo alloy Hip Stems cement type and cementless.

Acetabular cups and UHMWPE liners – Acetabular cup is manufactured from Ti-6Al-4V ELI and Liner is manufactured from Ultra-High Molecular Weight Polyethylene (UHMWPE). The UHMWPE insert (sizes 22 mm and 28 mm) are intended to be used in conjunction with MultiFit™ Total Hip System acetabular cups (sizes 42 mm to 60 mm in 2 mm increments) in cementless applications. UHMWPE liners are available in two types of Flat and 10° elevated.

Bipolar cups and liners – Bipolar cup is made of Cobalt Chromium Molybdenum (CoCrMo) and liner is made of Ultra-High Molecular Weight Polyethylene (UHMWPE) same as acetabular liner. Bipolar cups (sizes 42 mm to 55 mm 1 mm increments) are intended to be used with the bipolar liners (22 mm and 28 mm in diameter) of the MultiFit™ Total Hip System.

5. Indications for Use

The MultiFit Total Hip System **is intended to be cemented stem or uncemented stem use.**

The MultiFit Total Hip System is to replace a defective hip joint in the following cases:

1) Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head and nonunion of previous fractures of the femur.

2) Patients with congenital hip dysplasia, protrusion acetabuli, or slipped capital femoral epiphysis

3) Patients suffering from disability due to previous fusion

4) Patients with acute femoral neck fractures

6. Statement of Technological Comparison

Bench testing as listed in **Section 15** and **Appendix D**. was conducted in accordance with standard. It demonstrates substantial equivalence to the above listed predicate devices in terms of materials, design, indications for use and operational principles.

7. List of the bench tests conducted for the substantial equivalence to the predicate devices

1. Ace tabular system Push out test of Locking Mechanism according to ASTM F1820
2. Ball pull off test according to ASTM F2009
3. Bone screw axial pullout strength test according to ASTM F543
4. Bone screw torsion strength test according to the ASTM F543
5. Range of motion test according to the ISO 21535
6. Wear test according to the ISO 14242-1:2002-03 and ISO 14242-2:2000-10-05
7. Fatigue test according to the ISO 7206-4(2002) Implants for surgery – Partial and total hip joint prostheses – Part4: Determination of endurance properties of stemmed femoral components.
8. Fatigue test according to the ISO 7206-6(1992)- Implants for surgery -- Partial and total hip joint prostheses -- Part 6: Determination of endurance properties of head and neck region of stemmed femoral components
9. Oxidation index and accelerated ageing of UHMWPE according to ASTM F2102-01el and ASTM F2003-02
10. Ace tabular liner torsion test
11. Ace tabular system Lever out test
12. Bipolar system Push out test between ball and UHMWPE liner
13. Bipolar system Lever out test between ball and UHMWPE liner

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

OTIS Biotech Co., Ltd
% Mr. Srinivasareddy Krotha
514 Sihwa Industrial Complex 2Ba Block
Jeongwang-Dong, Siheung-si
Gyounggi-Do, Republic of Korea 429-450

JAN 5 2011

Re: K101472
Trade/Device Name: Multifit Total Hip System
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.
Regulatory Class: Class II
Product Code: LZO, JDI, KWY, KWZ
Dated: December 24, 2010
Received: December 30, 2010

Dear Mr. Krotha

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101472

4. Indications for Use

510(k) Number:

Device Name: **MultiFit™ Total Hip System**

The hip system is intended to be cemented stem or un cemented stem use.

Indications for Use:

The MultiFit Total Hip System is to replace a defective hip joint in the following cases:

1) Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head and nonunion of previous fractures of the femur;
2) Patients with congenital hip dysplasia, protrusion acetabuli, or slipped capital femoral epiphysis;
3) Patients suffering from disability due to previous fusion and previously failed endo-prostheses;
4) Patients with acute femoral neck fractures.

Prescription Use __Yes__ AND/OR Over-The-Counter Use __No__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101472